

REMARKS

The Office Action

Claims 83, 87, 88, 90, 101, and 102 are pending in this application. With this reply new claim 112 has been added. Claims 1-82, 84-86, 89, 91-100, and 103-111 were previously canceled. Claim 83 stands rejected under 35 U.S.C. § 112, first paragraph, for reciting new matter. Claims 83, 87, 90, 101, and 102 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claim 83 stands rejected under 35 U.S.C. § 102 for lack of novelty.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 83 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner asserts support is lacking for SEQ ID NO: 98 conjugated to a polylysine of 4-10 amino acid residues. Applicants have addressed this rejection by amendment of the claim 83.

Claim 83 has been amended to remove reference to SEQ ID NO 98.

In view of this amendment to claim 83, applicants request that the rejection for new matter be withdrawn.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 83, 87, 90, 101, and 102 stand rejected under 35 U.S.C. § 112, second paragraph for indefiniteness. The Examiner asserts (i) integers “4”, “5”, and “6” should appear as subscripts in claim 87, (ii) the formula for SEQ ID NO 99 in claim 90 does not match the formula in the specification with respect to the stabilizing portion of the sequence, and (iii) the use of the term “about” in claims 101 and 102 lacks antecedent basis in claim 83. Applicants have addressed these rejections by amendment of the claims.

Claim 87 has been amended so that integers “4”, “5”, and “6” appear as subscripts. Claim 90 has been amended to correct an error in SEQ ID NO 99. The stabilizing portion of this sequence has been amended to show that (Lys-Glu)₃ is -Lys-Glu-Lys-Glu-Lys-Glu-. Claims 101 and 102 have been amended to remove the term “about.”

In view of the amendments to the claims, applicants request that the rejection for indefiniteness be withdrawn.

Rejections Under 35 U.S.C. § 102

Claim 83 stands rejected under 35 U.S.C. § 102(e) for lack of novelty over U.S. Patent No. 5,688,760 (hereafter ‘Kemp’). Applicants have addressed this rejection by amendment of the claims.

Kemp describes a PTH peptide sequence that includes the segment Lys₄ within the peptide, but not at either terminus of the peptide.

Claim 83 has been amended to require that Z, the stabilizing peptide, consists of from 4 to 15 amino acid residues in addition to comprising the sequence Lys₄₋₁₀.

Claim 83, as amended, is novel in view of Kemp because, for example, the peptides disclosed by Kemp do not include within their sequence a Lys₄₋₁₀ segment within the 15 amino acid residues capping either terminus of the PTH peptide.

In view of this amendment to claim 83, applicants request that the rejection for lack of novelty be withdrawn.

Support for the Claim Amendments

Claims 83, 87, 90, 101, and 102 have been amended. Claim 112 has been added. No new matter has been added with these amendments.

Support for a stabilizing peptide, Z, bound by its C terminus to the N terminus end of X, as recited in claim 83, is found in the specification at page 19, line 27.

Support for a stabilizing peptide, Z, having from 4 to 15 amino acid residues, as recited in claim 83, is found in the specification at page 15, line 1.

Support for Leu-enkephalin-(Lys-Glu)₃ (SEQ ID NO: 99), as recited in claim 90, is found in the specification at page 22, line 24.

Support for a stabilizing peptide, Z, having from 4 to 6 lysine residues, as recited

in claim 112, is found in the specification at page 17, lines 16-23.

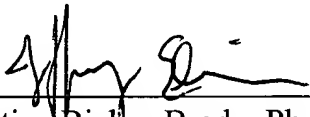
CONCLUSION

Applicants submit that the claims are now in condition for allowance and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for three (3) months, to and including November 21, 2005 (because November 19, 2005 falls on a Saturday), and a check in payment of the required extension fee. Applicant claims small entity status under 37 C.F.R. § 1.27.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Kristina Bicker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

Jeffrey J. Ellison, Reg. No. 51,649,
for Kristina Bicker-Brady